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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,866	05/04/2001	Ilya Chumakov	GENSET.15CDVI	1458

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EXAMINER

ZARA, JANE J

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

**Office Action Summary**

Application No.

09/849,866

Applicant(s)

Chumakov et al

Examiner

Jane Zara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on Jul 9, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-20 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on May 4, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>4</u> | 6) <input type="checkbox"/> Other:  |

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### **DETAILED ACTION**

Claims 10-20 are pending in the instant application.

#### ***Information Disclosure Statement***

The reference listed as No. 8 in the IDS filed August 8, 2001, lists a European search report and has been considered, but has been lined out because this is not a publication and will not be listed in the published patent as a reference.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 10, line 5, "said insert" lacks proper antecedent basis (perhaps replacing "said" with --an-- would be remedial).

In claim 13, line 2, it is unclear what "origin or replication" means (e.g. perhaps replacing "or" with --of-- would be remedial).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to a method of determining the copy number of a vector comprising a truncated lacZ gene which confers dark blue coloration to a host cell, when the truncated lacZ gene is present in high copy numbers. The claim does not describe elements which are essential to the function of the claimed invention, which comprise any truncation of the lacZ gene. The scope of the claim includes numerous structural variants and genus is highly variant because a significant number of structural differences between members of the genus is permitted. Concise structural features that could distinguish structures within the genus are missing from the claim. The specification fails to teach or adequately describe a representative number of species of the genus comprising any truncated lacZ gene product. And because the genus is highly variant, the description provided is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus claimed. Thus, applicant was not in possession of the claimed genus.

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Claims 10, 12-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining the presence of an insert into a vector, whereby the vector comprises a *strA*<sup>+</sup> gene or comprises hybridization sites for sequencing primers to allow sequencing of the DNA insert, does not reasonably provide enablement for determining a change in copy number of a vector or determining the presence of an insert into a vector comprising detecting any selectable marker, comprising detecting expression by blue color formation of any truncation of *lacZ*, or comprising determining the copy number of the vector. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to methods for determining a change in copy number of a vector or determining the presence of an insert into a vector comprising detecting any selectable marker, comprising detecting blue color formation of any truncation of *lacZ*, or comprising determining the copy number of the vector.

The following factors have been considered in determining that the specification does not enable the skilled artisan to make and/or use the invention over the scope claimed.

**The state of the prior art and the predictability or unpredictability of the art.** The following reference is cited herein to illustrate the state of the art of correlating a selection marker with vector copy number. Olsen teaches the unpredictability of antibiotic resistance and gene copy number in different bacterial strains, where, “disparate properties” in various strains of

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bacteria have been documented (See Olsen at col. 16, lines 56-66). Olsen also teaches that “minute changes in enzyme activity within the cell wall will cause a considerable increase in the level of resistance” of a host bacteria (See Olsen at col. 16, lines 56-66).

**The amount of direction or guidance presented in the specification AND the presence or absence of working examples.** Applicants have not provided guidance in the specification toward a method for determining a change in copy number of a vector or determining the presence of an insert into a vector comprising detecting any selectable marker, comprising detecting blue color formation of any truncation of lacZ, or comprising determining the copy number of the vector. The specification teaches a subcloning vector (pGenDel1), which comprises a strA<sup>+</sup> gene and the lacZ gene truncation of SEQ ID NO: 7, and which vector further comprises sequencing and amplifying primer hybridization sites. The specification fails to teach the determination of copy number of any vector comprising any selection marker, or any lacZ truncation. The specification fails to teach the identification of any vector containing any DNA insert comprising screening the vector for a second copy number. One skilled in the art would not accept on its face the examples given in the specification of the determination of inserting fragments into the vector pGenDel1 by detecting the blue coloration in transformed (appropriate bacterial hosts) by lacZ activity from the expression of SEQ ID NO: 7, and by determining the ability of transformed bacteria to grow on different concentrations of streptomycin as being correlative or representative of the ability to determine a change in copy number of a vector or determining the presence of an insert into a vector comprising detecting any selectable marker, or

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comprising detecting blue color formation of any truncation of lacZ, or comprising determining the copy number of the vector. The specification as filed fails to provide any particular guidance which resolves the experimental unpredictability associated with using any selection marker, or using any truncation product of lacZ to determine copy number or the presence of any insert into a vector.

**The breadth of the claims and the quantity of experimentation required.** The breadth of the claims is very broad. The claims are drawn to methods for determining a change in copy number of a vector or determining the presence of an insert into a vector comprising detecting any selectable marker, comprising detecting blue color formation of any truncation of lacZ, or comprising determining the copy number of the vector. The quantity of experimentation required to practice the invention as claimed would require the de novo determination of a representative number of truncation products of lacZ whereby dark blue and light blue colony color determine copy number or insertion of a DNA fragment into a vector, and the de novo determination of the relationship between selection markers and dose concentration of any selection reagent in suitable host bacteria whereby high and low copy number is determined. Since the specification fails to provide any particular guidance for these experimental variables and conditions, and since determination of these factors is highly unpredictable, it would require undue experimentation to practice the invention over the broad scope claimed.

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### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 100-107 of U.S. Patent No. 6,022,716. Although the conflicting claims are not identical, they are not patentably distinct from each other because the both sets of claims are drawn to methods of identifying vectors containing a DNA insert comprising subjecting a plurality of vectors having a first copy number to insertion conditions and identifying at least some vector or vectors containing an insert by screening for a second copy



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number, and are drawn to methods of determining the copy number of a vector in a host cell comprising screening the vector for a change in copy number comprising the selection marker streptomycin resistance, or comprising a comparison in transduced host cell colony formation due to lacZ expression.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Olsen (USPN 4,567,141).

Olsen teaches a method of determining copy number of a vector comprising a strA gene wherein host cells are able to grow in the presence of streptomycin when the strA gene is present in low copy number, but unable to grow in streptomycin when the strA gene is present in high copy numbers (see col. 16, line 3-col. 17, line 36).

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### ***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

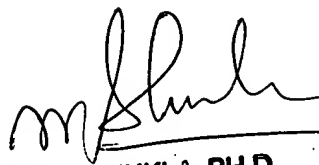
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a

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general nature or relating to the status of this application should be directed to the Group  
receptionist whose telephone number is (703) 308-0196.

*JZ*

October 19, 2003

  
**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**